

WHAT WE CLAIM IS:

1. A sample collection device for assay comprising:
 - a holding portion having a first end and a second end;
 - a retaining portion coupled to the holding portion second end and selectively configurable between at least an extended size and a contracted size; and
 - an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size;
 wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size.
2. The sample collection device for assay of claim 1, wherein the retaining portion includes a blocking portion defining a sample retaining size of the retaining portion and preventing movement of the retaining portion to a size that is less than the sample retaining size, the sample retaining size being formed when the blocking portion engages with the holding portion second end.
3. The sample collection device for assay of claim 1, wherein the retaining portion includes a discharge member spaced from the holding portion second end, the collector member being disposed between the discharge member and the holding portion second end, wherein when the retaining portion is moved from the extended size to the sample retaining size, a portion of the sample in the retaining portion suitable for assay is discharged from the collector member.
4. The sample collection device for assay of claim 3, wherein the collector member is made from a fluid absorbing material and the sample is discharged from the collector member by squeezing the collector member between the discharge member and the holding portion second end.

5. The sample collection device for assay of claim 2, wherein the collector member contains a third amount of sample when the collector member size is substantially equal to the sample retaining size, and

wherein the second amount of sample is usable for a primary assay and the third amount of sample is usable for a secondary assay.

6. The sample collection device for assay of claim 2, wherein the retaining portion includes an elongate member, the blocking portion includes a raised portion formed on the elongate member, and the holding portion second end includes a wall sized to engage with the raised portion when the retaining portion is moved from one of the extended size and the contracted size to the sample retaining size.

7. The sample collection device for assay of claim 1, wherein the holding portion includes a housing defining an opening for slidably receiving the retaining portion so as to permit the retaining portion to be selectively movable between at least one of the extended size and the contracted size.

8. The sample collection device for assay of claim 1, wherein the retaining portion includes a discharge member spaced from the holding portion second end, the collector member being disposed between the discharge member and the holding portion second end, wherein when the retaining portion is moved from the extended size to the contracted size, a sample portion sufficient for assay is discharged from the discharge member.

9. The sample collection device for assay of claim 8, wherein the retaining portion is made from a fluid absorbing material and the sample portion is discharged from the discharge member by squeezing the collector member between the discharge member and the holding portion second end.

10. The sample collection device for assay of claim 1, wherein the retaining portion includes a wall spaced at a first length from the holding portion second end when the retaining portion is

in the expanded size and the wall is spaced at a second length from the holding portion second end when the retaining portion is in the contracted size.

11. The sample collector device for assay of claim 10, wherein the retaining portion is an elongate member having a proximal end adjacent the holding portion second end and a perforated disc-like piece formed at a distal end, the perforated disc-like piece comprising the wall, and

wherein the collector member is made from a fluid absorbing material that is movable along the elongate member when the collector member has the first collection size.

12. The sample collector device for assay of claim 1, wherein the collector member has a first length when the collector member has the first collection size, the collector member has a second length when the collector member has the second collection size, and the retaining portion describes an extended length when the retaining portion has the extended size,

wherein a sufficient sample is collected for assay when the second length is substantially equal to the extended length.

13. The sample collector device for assay of claim 1, wherein the collector member size is reduced from the second collection size to the first collection size when the retaining portion is configured from the extended size to the contracted size.

14. A test device in combination with the sample collector device for assay of claim 1, the test device being adapted to connect with the sample collection device and including a tester to assay for analytes in the sample, the test device including

an opening sized to receive the holding portion;

a discharge surface adapted to engage with the retaining portion, wherein the collector member second collection size is substantially equal to the retaining portion extended size before engaging the retaining portion with the discharge surface, and the sample collector is in fluid communication with the tester and the retaining portion is configured in the contracted size when the retaining portion is engaged with the discharge surface.

15. The test device in combination with the sample collector device for assay of claim 14, wherein the holding portion second end includes an engagement surface and the test device includes a mating surface adapted to engage with the engagement surface, wherein the holding portion is fixed to the test device when the engagement surface engages with the mating surface.

16. The test device in combination with the sample collector device for assay of claim 15, wherein the mating surface engages with the engagement surface by elastic deformation of at least one of the mating surface and the engagement surface.

17. The test device in combination with the sample collector device for assay of claim 15, wherein the holding portion is fixed to the test device by a friction fit between the engagement and mating surfaces.

18. The test device in combination with the sample collector device for assay of claim 15, wherein the collector member second collection size is substantially equal to the retaining portion extended size when the mating surface engages with the engagement surface.

19. The test device in combination with the sample collector device for assay of claim 15, wherein the holding portion includes a second engagement surface and the test device includes a second mating surface adapted to engage with the second engagement surface,
wherein when the second engagement surface is in contact with the second mating surface, the discharge surface engages with the retaining portion.

20. The test device in combination with the sample collector device for assay of claim 14, wherein the tester is a lateral flowstrip in fluid communication with the collector member when the holding portion is fixed to the test device and the retaining portion is in the contracted size.

21. The test device in combination with the sample collector device for assay of claim 14, wherein the test device further includes an ampoule containing fluid and the ampoule is violated when the collector member is equal to the first collection size.

22. The test device in combination with the sample collector device for assay of claim 14, wherein the holding portion first end comprises a handle and the first end is removable from the second end.

23. The sample collection device for assay of claim 1, wherein the second amount of sample corresponds to an assay sample that is substantially contained in the collector member, the assay sample being transferable from the collector member to a test device for assay of the assay sample.

24. The sample collection device for assay of claim 1, wherein the second amount of sample includes a first assay sample and a second assay sample.

25. The test device in combination with the sample collector device for assay of claim 14, wherein the collector member has the first collection size when the sample collector is in fluid communication with the tester.

26. An apparatus for assay of analytes in a sample, the sample originating from a sample source, comprising:
 a test cassette including a test device;
 a collector including a housing, the collector being exposed to the sample source when collecting the sample and the collector being adapted for expression of the collected sample from the collector to the test cassette, the collector containing the sample;

a movable portion of the collector disposed in operative proximity to the sample and being coupled to the collector when the collector is exposed to the sample source and when the sample is expressed from the collector to the test cassette, the movable portion being movable between a first position and second position relative to the housing, wherein when the movable portion is in the second position, the sample collector contains a second portion of sample and when the movable portion is in the first position, the collector member contains a first portion of sample; and

a portal of the test cassette adapted to receive the collector; and
 means for preventing removal of the collector from the test cassette.

27. The apparatus according to claim 26, wherein the test device includes a lateral assay strip.
28. The apparatus according to claim 26, wherein the means for preventing removal of the collector from the test cassette includes engaging the housing with the portal.
29. The apparatus according to claim 28, wherein the means for preventing removal of the collector from the test cassette further prevents removal of the housing and movable portion from the test cassette.
30. The apparatus according to claim 29, wherein the movable portion is a plunger.
31. The apparatus according to claim 26, wherein the means for preventing removal of the collector from the portal includes a ridge formed on one of the portal and the housing that engages the other of the housing and the portal.
32. The apparatus according to claim 26, further comprising a handle that is releasably securable to the housing, the handle being secured to the collector when the collector is exposed to the sample source and the collector is detached from the handle after expression of the sample from the collector to the test cassette.
33. The apparatus according to claim 26, the collector including a fluid absorbing portion disposed on the movable portion, the fluid absorbing portion containing a first and second volume of sample when the movable portion is in the second position and the fluid absorbing portion is devoid of the second volume of sample when the movable portion is in the first position.
34. The apparatus according to claim 26, wherein the movable portion is a plunger.

35. The apparatus according to claim 26, wherein at least one of the portal and collector includes a fluid seal part for inhibiting escape of the sample from the test cassette after expression of the sample from the collector to the test cassette.

36. An apparatus for assay of analytes in a sample, comprising:

a collector including a fluid collecting part for collecting the sample from a sample source;

a handle connected to the collector for placing the collector and fluid collecting part into fluid communication with a sample source;

a test cassette including a test device for assay of the sample, the sample being delivered to the test cassette by the handle and collector for expression of the sample to the test device;

a well of the test cassette, the well defining an enclosure having an opening for access to a substantially enclosed containment portion of the well for containing the collector and fluid collecting part therein and engaging the collector so as to prevent removal of the collector from the well, the collector and fluid collecting part being engaged with the containment portion when the sample is expressed to the test device.

37. The apparatus of claim 36, wherein the sample source is an oral cavity.

38. The apparatus of claim 36, wherein the fluid collecting part is a sponge.

39. The apparatus of claim 36, wherein the test device includes a sample receiving pad at least partially disposed within the well, an absorbent pad distal from the well and a fluid conduit extending between the sample receiving pad and absorbent pad, wherein the absorbent pad draws the sample from the sample receiving pad to the absorbent pad by capillary action when the sample is in fluid communication with the sample receiving pad.

40. The apparatus of claim 36, wherein the handle is connected to the collector by a connector adapted for removably coupling the handle to the collector.

41. The apparatus of claim 40, wherein the well includes a first end located at the opening, a second end proximate to the test device, and the containment portion has a lengthwise extent that extends between the first and second ends and parallel to a first axis,

wherein when the collector is engaged with the containment portion, the handle is releasable from the collector by at least rotating the handle about the first axis.

42. The apparatus of claim 41, further including a means for preventing rotation of the collector relative to the well when the handle is removed from the collector by the at least rotating the handle about the first axis, the means for preventing rotation including a groove formed on one of the containment portion and the collector, the groove extending parallel to the first axis.

43. The apparatus of claim 36, wherein the test device includes an ampoule positioned in the well, the ampoule containing a buffer solution, and the collector includes a perforated disc,

wherein when the collector is engaged with the containment portion, the perforated disc is engaged with the ampoule and the sample is in fluid communication with the buffer solution.

44. The apparatus of claim 36, wherein the collector is sized to be snugly received within the containment portion such that when the sample is in fluid communication with the test device, the sample is inhibited from escaping from the test cassette through the well opening.

45. The apparatus of claim 36, wherein the well is integrally formed with the test cassette.

46. A sample collection device for assay comprising:

a holding portion having a first end and a second end;

a retaining portion coupled to the holding portion second end and selectively configurable between at least an extended size and a sample retaining size, the sample retaining size being smaller than the extended size;

a blocking portion disposed on the retaining portion, the blocking portion being spaced from the holding portion second end when the retaining portion is configured in the extended

size and the blocking portion being engaged with the holding portion second end when the retaining portion is configured in the sample retaining size; and

an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of sample and a second collection size when the collector member has a second amount of sample;

wherein the collector member has the second collection size when the blocking member is spaced from the holding portion second end and the collector member has the first collection size when the blocking member is engaged with the holding portion second end,

wherein the first amount of sample is sufficient for a first assay of sample and the second amount of sample is sufficient for a second assay of the sample.

47. The sample collection device for assay of claim 46, wherein the blocking portion is formed on the retaining portion.

48. The sample collection device for assay of claim 47, wherein the retaining portion includes a first part including the blocking portion and a second part that is smaller than the first part and wherein the second part is received within the holding portion when the retaining portion is configured from the extended size to the sample retaining size.

49. The sample collection device for assay of claim 46, the retaining portion further comprising

a first elongate portion having a first length and a first width dimension wherein the first length substantially corresponds to the sample retaining size, and

a second elongate portion having a second width dimension,

wherein the holding portion second end defines an opening sized for slidably receiving the retaining portion, the opening defining a width dimension that is smaller than the first width and greater than the second width.

50. The sample collection device for assay of claim 49, wherein the retaining portion is a cylinder and the first width corresponds to a first diameter of the cylinder and the second width corresponds to a second diameter of the cylinder.

51. The sample collection device for assay of claim 46, wherein when the collector member has a first collection size and the retaining portion is configured from the extended size to the sample retaining size, the collector member is configured from the second collection size to the first collection size and a sample sufficient for the first assay is expressed from the collector member.

52. The sample collector device for assay of claim 46, wherein the collector member is made from a fluid absorbing material and the retaining portion expresses fluid sufficient for assay of sample from the collector member when the retaining portion is configured from the extended size to the sample retaining size.

53. A method for collection and delivery of a sample to a tester for assay of the sample, comprising:

providing a collection device including a fluid collector;

providing a test device housing the tester, the test device including a well for receiving the collection device and fluid collector and providing access to the tester, the well including a wall extending from an upper well end to a lower well end;

collecting the sample from a sample source including exposing the collection device and fluid collector to the sample source;

disposing a mating surface on one of the wall and the collection device; and

transferring the sample to the tester including the step of locking the collection device and the fluid collector in the well by engaging the other of the wall and the collection device with the mating surface and expressing the sample into the well so as to place the sample in fluid communication with the tester.

54. The method for delivery of a sample to a tester for assay of the sample of claim 53, wherein the tester includes a sample receiving pad and an absorbent pad, further including the steps of

forming a first and second part of the test device, the first part including the well and the second part including the tester, the second part being at least partially devoid of sample after the expressing the sample into the well step,

disposing at least a portion of the sample receiving pad in the well and the absorbent pad at a location distal from the well, and

disposing a porous strip between and connecting the absorbent pad and sample receiving pad,

wherein the sample migrates from the sample receiving pad to the absorbent pad through capillary action after the expressing the sample into the well step.

55. The method for delivery of a sample to a tester for assay of the sample of claim 53, wherein the collection device includes a movable portion that is movable between a first and second position, the movable portion being in the second position when performing the collecting the sample from a sample source step, wherein the transferring the sample into the well step includes the step of

moving the movable portion from the second position to the first position.

56. The method for delivery of a sample to a tester for assay of the sample of claim 53, wherein the mating surface is a first raised portion disposed on the well wall, further comprising the step of

disposing a second raised portion on the collection device,

wherein the engaging step includes engaging the first raised area with the second raised area.

57. The method for delivery of a sample to a tester for assay of the sample of claim 56, wherein the disposing a second raised portion on the collection device and the disposing a first raised portion steps further include the steps of forming the first and second raised portions on the well wall and collection device, respectively.

58. The method for delivery of a sample to a tester for assay of the sample of claim 56, wherein the engaging step further includes the step of forcibly pressing the second raised portion into the first raised portion,

wherein the step of forcibly pressing the second raised portion into the first raised portion results in a locking of the collector to the well wall by at least one of elastically deforming the first raised portion as the second portion is pressed into the first portion and forming a friction fit between the first and second raised portions.

59. The method for delivery of a sample to a tester for assay of the sample of claim 53, further including the steps of

providing a handle for the collector, the handle being attached to the collector during the collecting the sample step, and

removing the handle from the collector after the transferring step.

60. The method for delivery of a sample to a tester for assay of the sample of claim 53, the test device including a lower portion associated with the tester, the lower portion positioned within the well, wherein the expressing step further includes the steps of

engaging the collection device with the lower portion to thereby express sample from the collection device to the test device.

61. The method for delivery of a sample to a tester for assay of the sample of claim 60, the collection device including a retractable end and a housing, the retractable end being movable relative to the housing and the fluid collector is disposed on the retractable end, wherein the expressing the sample to the test device further includes the step of

engaging the retractable end with the lower portion to thereby displace the retractable end relative to the housing.

62. The method for delivery of a sample to a tester for assay of the sample of claim 53, wherein the expressing the sample step includes the step of pushing the collection device into the test device to thereby place the sample in fluid communication with the tester.

63. The method for delivery of a sample to a tester for assay of the sample of claim 53, wherein the tester includes an ampoule and the transferring step further comprising the step of crushing the ampoule with the collection device.

64. A method for collecting a sample adequate for assay, comprising the steps of providing a sample collector for collecting sample, the sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample for assay is contained in the sample collector;

providing a collector holder, the collector holder including a sample area for indicating whether the sample collector has collected a sample sufficient for assay, the sample area defining a sample adequacy size;

disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area;

collecting a sample on the sample collector; and

comparing the size of the sample collector to the sample adequacy size and if the sample adequacy size is approximately equal to the second size then an adequate sample is collected for assay.

65. The method for collecting a sample adequate for assay of claim 64, the collector holder including a wall and a housing having a first end and a second end, the wall being spaced from the housing second end by a length corresponding approximately to a sample adequacy length and the first and second size of the sample collector corresponds to a first and second length of the sample collector, respectively,

wherein the disposing the sample collector within the sample area corresponds to disposing the sample collector between the housing second end and the wall, and

wherein the comparing step further includes comparing the length of the sample collector to the sample adequacy length and if the sample adequacy length is approximately equal to the second length then an adequate sample is collected for assay.

66. The method for collecting a sample adequate for assay of claim 64, wherein the sample area is configurable between a contracted area size and the sample adequacy size.

67. The method of claim 64, wherein the collector member is a sponge and the comparing the size of the sample collector to the sample adequacy size corresponds to comparing the sponge size to the sample adequacy size.

68. A method for collecting and assay of a sample collected from a sample source, comprising the steps of:

- providing a sample collector including a fluid absorbing portion;
- collecting the sample including the step of exposing both the sample collector and fluid absorbing portion to a sample source;
- providing a test device including a sample receiving area and an assay strip for assay of the collected sample;
- locking the sample collector and fluid absorbing portion to the sample receiving area; and
- reading the results displayed on the assay strip.

69. A method for assay of a sample of claim 68, wherein the collector holder includes a first part and a removable handle, further including the step of removing the handle from the first part after the locking the collector holder and sample collector in the well step.

70. A method for assay of a sample of claim 68, wherein the locking step discharges the sample from the sample collector so as to place the sample in fluid communication with the assay strip.

71. The sample collection device for assay of claim 1, wherein the collector member is a sponge.

72. The sample collection device for assay of claim 71, wherein the first collection size corresponds to a dry sponge.